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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,541	STRAND ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14,16,17 and 39-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14,16,17 and 39-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, IDS, Sequence Listing, and substitute CRF, filed 7/30/07 are acknowledged.

2. Upon reconsideration Claims 7, 10, 17, 23, 29, and 36 are rejoined.

Claims 1, 3-14, 16, 17, and 39-60 are under examination.

3. The substitute Title and Sequence listing are found to be acceptable.

4. In view of Applicant's amendment, all previous rejections have been withdrawn. The following are new grounds for rejection.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-14, 16, 17, 39-60 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/41813 (IDS).

WO 01/41813 teaches a method of stabilizing or improving the health-related quality of life of an individual with SLE comprising administering LJP-394 at a weekly dose of about 3 mg/kg or higher, including a dosage range of about 5-100mg/kg, 10mg/kg weekly, or about 200 mg to about 500 mg weekly, or about 300 mg weekly (see particularly page 40). LJP-394 comprises the dsDNA epitope of SEQ ID NO:1 and SEQ ID NO:2 conjugated to the valency platform of Claim 7 (see particularly the Claims). The reference teaches the additional limitations of the claims including sustained reduction of symptoms for at least about 24 weeks and stabilization after renal flare (Figures 14 and 15). The figures also show an at least about 20% or 30% reduction below baseline. Note that Claims 11, 12, 30, and 38 do not recite the actual use of SF-36 to measure stabilization or improvement but only that said stabilization of improvement is detectable, i.e., could be detected, employing said form.

Accordingly said claims are included in the rejection.

The reference clearly anticipates the claimed invention.

In response to a previous similar rejection, Applicant argues that the reference does not show sustained reduction of circulating anti-dsDNA antibodies.

Said reduction would be the inherent outcome of administering the same composition as that used in the instant application at the same dosages for the same timeframes.

Applicant argues that the reference does not teach or suggest stabilizing or improving health-related quality of life. Again, said improvement or stabilization would be inherent. Additionally, reduction of renal flare could most certainly be considered to be "improving health-related quality of life" to an SLE patient.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-64 of U.S. Patent No. 7,081,242. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claims of the '242 patent encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

In response to a previous similar rejection Applicant argues that the '242 patent does not teach sustained reduction of circulating anti-dsDNA antibodies.

Said reduction would be the inherent outcome of administering the same composition as that used in the instant application. Additionally, the optimization of dosages and timing of administration so as to achieve sustained efficacy would be obvious to the ordinarily skilled artisan.

9. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 10/814,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '555 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/081,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '309 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-27 of U.S. Patent Application No. 11/347,426. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '426 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '699 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 11/565,467. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '467 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/613,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '987 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1, 3-14, 16, 17, 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/562,174. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the claims of the '987 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Regarding sections 9-15 above, in response to previous similar rejections, Applicant requests that the provisional rejections be withdrawn.

The provisional rejections set forth above are proper for the reasons set forth above.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1, 3-14, 16, 17, 39-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

a) all claims include a limitation of a dosage of x mg/kg, e.g., 3 mg/kg in Claim 1. It is unclear what the kg refers to, i.e. 3 mg of conjugate per kg of what?

b) the method of Claim 47, which depends from Claim 1, appears to remove the limitation that the conjugate comprise both SEQ ID NOS:1 and 2.

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1, 3-14, 16, 17, 39-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter written description rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

a) a method … wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month (Claims 1, 39, 40, 45, 55, and 60), … and the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual (Claims 1, 39, 40, and 55).

b) a method … administering a dose of about 5 mg/kg to about 100 mg/kg (Claims 41, 53, and 56).

c) a method … administering a dose of about 10 mg/kg or higher (Claim 42, 54, and 57).

d) a method … administering a dose of about 200 mg to about 500 mg (Claim 58).

e) a method … administering a dose of about 300 mg (Claim 59).

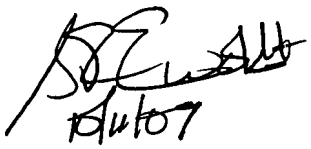
Applicant cites various support throughout the specification. Said cites do not disclose the specific limitations of the claims. In particular the cites, e.g., paragraph [219], do not disclose the specific dosages of the claims.

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

22. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



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